

REMARKS/ARGUEMENT

I. Status of the Claims

Claims 4 – 6, 8 – 11 and 14 are pending in the subject application.

Claims 8, 10 and 11 are allowed.

Claims 4 – 6, 9 and 14 are rejected.

In the current response:

Claim 4 and 9 are amended for clarification.

No new matter is entered.

Applicants will sequentially address the issues raised by the Examiner.

II. The 35 U.S.C. §112, first paragraph Claim Rejections

Claim 9 was rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. Specifically, the Examiner contends “ The breadth of the claims: The instant claims are deemed very broad since these claims reads on protecting skin or hair from senescence ...”. “The specification does not enable any person skilled in the art ... to use the invention commensurate in scope with these claims ... to fully practice the instant invention without undue experimentation.”

Claim 9 has been amended as the following for further clarification:

“A method for intensifying SOD activity or reducing MDA level of the skin or hair in a subject ~~of protecting skin or hair from senescence~~ comprising administering to a subject a therapeutically effective amount of total triterpenoid sapogenins extracted from bamboo, wherein total triterpenoid sapogenins is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, said total triterpenoid sapogenins comprising 5-35% friedelin and 1-10% lupenone as determined by GC-MS to intensify SOD activity or to reduce MDA level of the skin or hair, wherein said therapeutically effective amount of total triterpenoid sapogenins is administered externally onto the skin or hair in a daily cosmetic.”.

Support of amended claim 9 can be found in line 1 through line 3 of paragraph [0032], in line 14 of paragraph [0044] and in line 6 of paragraph [0094] through line 6 of paragraph [0115] of the Specification (Example 6 with Table 9).

III. The 35 U.S.C. §103 (a) Claim Rejections

Claim 4 – 6 and 14 were rejected under 35 U.S.C. §103 (a), as being unpatentable over the reference of Staack Reis Machado et al. (EP 1122259 A2) (referred as Machado) in view of Ohmoto et al. (Shoyakugaku Zasshi (1974), 28(1), pages 1-6, abstract only).

Applicants carefully reviewed the cited reference and respectfully submit that the cited reference does not teach or suggest the present invention. Applicants obviate these rejections with the following amendments and remarks.

Claim 4 is drawn to a method of preparing materials from a natural origin, which is bamboo, and extracting total triterpenoid sapogenins from bamboo. In order to further clarify the features of the present invention, Claim 4 is amended as the following:

“A method of extracting total triterpenoid sapogenins from bamboo comprising:

- (a) selecting bamboo material from the group consisting of *Phyllostachys*, *Bambusa* and *Dendrocalamus* genus of Gramineae family;
- (b) preparing bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material by comminuting the bamboo material into bamboo shaving powder;
- (c) drying the bamboo shaving powder;
- (d) extracting free triterpenoid sapogenins from the bamboo shaving powder by mixing the bamboo shaving powder with supercritical CO₂ fluid and an entrainer in the amount of 5 – 15 % (v/v) of CO₂ until the free triterpenoid sapogenins is dissolved in the CO₂ fluid at temperature 50 – 60 degree C and pressure 25 – 35 Mpa;
- (e) separating total triterpenoid sapogenins from the CO₂ fluid containing free triterpenoid sapogenins by changing the temperature of the CO₂ fluid to 35 – 45 degree C and the pressure to 5 – 10 Mpa to gasify the CO₂;

(f) collecting a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone.”

The amended Claim 4 is supported by descriptions in line 1 through line 3 of paragraph [0027], page 4, line 1 through line 10 of paragraph [0042], page 5, line 1 through line 3 of paragraph [0046], page 5 of Example 1.A., line 3 through line 4 of paragraph [0047], page 5 of Example 1.B., line 4 of paragraph [0048], page 5 of Example 1.C. of this application. Please note that the starting materials for the process are pole, branch, leaf, shoot, shoot sheath, root or a mixture of bamboo. The preparation steps (steps a, b and c of claim 4) include selecting a plant of natural origin, comminuting the raw materials, and drying them. These preparation steps do not require either high temperature treatment or steam cooking operation. The total triterpenoid sapogenins is then extracted from bamboo shaving powder “under the supercritical condition after dryness and comminution” ((Page 5, line 1 through line 3 of paragraph [0046], line 3 through line 4 of paragraph [0047] and line 4 of paragraph [0048])). As described in Example 1A, 1B, 1C and 2, the claimed method provides efficient extraction so that high accuracy and quality products of total triterpenoid sapogenins can be obtained.

In contrast, Machado’s reference teaches a method “to extract the ceroid fraction of cork smoker wash solids and to recover long chain aliphatic alcohols and diterpenoid and triterpenoid compounds contained in said ceroid fraction.” (Machado, claim 1) The examiner states: “This implies that tripenoids can be extracted or isolated from natural origins such as from plants (e.g. bamboo plant).” However, the preparation steps of the plant of natural origin, which is virgin cork, taught by Machado require a high temperature and steam cooking operation. “The raw material is virgin cork resulting from cork tree pruning operation,... In production of cork agglomerates, a stream of steam at about 400 degree C is passed through the cork granules.” This preparation step results in cork smoker wash solids for further extraction. (Machado, page 2, column 1, paragraph [0002], line 16 – 30).

High temperature and steam cooking operation steps are necessary for Machado to prepare the raw material for extracting long chain aliphatic alcohols and diterpenoid and triterpenoid compounds. Machado is silent about preparing materials from natural

origins such as plants (e.g. bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material) by comminuting the material into powder WITHOUT high temperature and steam cooking operation. Machado is also silent about drying step as cited by step c in amended claim 4 of the present invention. Machado's method is, at least, different from the present invention in terms of selecting a plant of natural origin, preparing the plant of natural origin, and the substances extracted from the natural origin.

Ohmoto et al. disclose "Triterpenoids and the related compound from gramineae plants" (Ohmoto, abstract) The Examiner states: "It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Staack Reis Machado et al. and Ohmoto et al., to have used the method of Staack Reis Machado to extract triterpenoids from any plant such as bamboo in order to use them to treat condition such as rheumatoid disease, based on factors such as availability, cost, convenience, and/or need." However, since Machado's method uses different plant of natural origin and different preparation processes in comparison with the present invention, modifications have to be made in order to produce "a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone" as cited in claim 4 of the present invention. The modifications are not merely changing the physical parameters such as temperature, concentration, concentration, time, and repetition or types of extractions as discussed above. Motivations for such modifications are not taught or suggested by either Machado's or Ohmoto's references.

In addition, Ohmoto is silent about the percentage of total triterpenoid sapogenins in bamboo material, nor suggests to utilize supercritical CO₂ fluid to extract "a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone" as cited in amended claim 4 of the present invention.

The standard for making an obviousness rejection is currently set forth in MPEP 706.02(j):

To establish a prima facie case of obviousness, *three basic criteria* must be met. *First*, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *Second*, there must be a reasonable expectation of success. *Finally*, the prior art reference (or references when combined) *must teach or suggest all the claim limitations*. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (emphasis added)

See also, KSR International Co. v. Teleflex Inc., No. 04-1350, 550 U.S. (2007)

Accordingly, motivation coming from the applicant's own disclosure is not sufficient to establish a prima facie case of obviousness under 35 USC §103. Nor is it sufficient that those of ordinary skill in the art had the capability to combine and modify the referenced method or understand the advantage of the combination and modification.

Based on the forgoing discussions, it is respectfully contended that the cited references (Machado and Ohmoto) either by themselves or combined together do not teach or suggest all of the limitations recited in the amended claim. Therefore, amended claim 4 meets the test of patentability over the cited references under 35 U.S.C. §103(a). Reconsideration and withdrawal of the rejection of claim 4 is respectfully requested.

Claim 5, 6 and 14 are dependent on Claim 4, therefore are also patentably distinct over the reference of Machado et al in view of Ohmoto et al. for at least the same reasons as those set forth with respect to claim 4. Reconsideration and withdrawal of the rejection of claim 5, 6 and 14 are respectfully requested.

IV. Allowable Subject Matter

The Applicants thank the Examiner for holding that Claims 8, 10 and 11 to be unobvious over the prior art of record and that Claims 8, 10 and 11 are allowed.

V. Conclusion

The applicants respectfully request reconsideration of the claims in view of the amendments and remarks made herein. A notice of allowance is earnestly solicited.

In the event that any fee is deemed due for this Response, the commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Remark to Deposit Account No. 502869.

Should the Examiner believe that further discussion of any remaining issue would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,

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